DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 8, 2015

Stryker Instruments
Ms. Jeanne S. Warner
Regulatory Affairs Manager
4100 E. Milham Ave.
Kalamazoo, Michigan 49001

Re: K143399
Trade/Device Name: Stryker Footed Attachments and Cutting Accessories
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered Simple Cranial Drills, Burrs, Trephines, and Their Accessories
Regulatory Class: Class II
Product Code: HBE, ERL
Dated: April 7, 2015
Received: April 8, 2015

Dear Ms. Warner,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143399

Device Name
Stryker Footed Attachments and Cutting Accessories

Indications for Use *(Describe)*
The Footed Attachments and Cutting Accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE®) Console and electric and pneumatic motors. When used with these motors, the Footed Attachments and Cutting Accessories are intended to cut bone in the following manner: drilling, reaming, decorticating, shaping, dissecting, shaving and smoothing for the following medical applications: Neuro; Spine; Ear, Nose, and Throat (ENT) / Otology /Neurotology/Otorhinolaryngology; Craniofacial (bones of the skull and supraorbital region); and Sternotomy.

Specific applications include Craniotomy/Craniectomy, Pterional Craniotomy, Sub Occipital/Retro Sigmoid/Posterior Fossa Craniotomy, Sphenoid Wing Dissection, Laminotomy/Laminectomy, and Orthopedic Spine.

These devices are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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4100 E. Milham Ave.
Kalamazoo, MI 49001
t: 269 323 7700 f: 269 389 5412
www.stryker.com

510(k) Summary

510(k) Owner: Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, MI 49001
(p) 269-323-7700
(f) 269-389-5299

Contact Person: Jeanne S. Warner
Regulatory Affairs Manager

Registration Number: 1811755

Date Summary Prepared: May 07, 2015

Trade Name(s): Stryker Footed Attachments and Cutting Accessories

Common Name: Powered simple cranial drills, burrs, trephines, and their accessories.

Classification Data:

Product Code	Device	Regulation Number	Class
HBE (Primary Code)	*Drills, burs, trephines, and accessories (simple, powered)*	21 CFR 882.4310	II
ERL (Secondary Code)	*Drill, Surgical, ENT (Electric or Pneumatic) including*	21 CFR 874.4250	II

Predicate Device:

510(k) number	Product code	Trade name	Manufacturer
K112593	ERL	Stryker® Consolidated Operating Room Equipment (CORE) System	Stryker Instruments

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t: 269 323 7700 f: 269 389 5412
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Reference Device-Anspach:

Trade Name:	Anspach Dissecting Tools
Type:	Reference Device
510(k) Number:	K113476
Description:	The primary predicate device has successfully addressed decision points 1 to 4 in the 510(k) Decision Making Flowchart as per FDA) Guidance for Industry and FDA Staff, The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], dated July 28, 2014. However, the dimensions, material and technological characteristics of 2.3mm and 3.0mm spiral routers are compared to Anspach Dissecting Tools, which are cleared through the 510(k), K113476.

Reference Device-Medtronic:

Trade Name:	Medtronic Footed Attachments and Cutting Tools
Type:	Reference Device
510(k) Number:	K081475
Description:	Medtronic Cutting Tools have been used as a reference device since these devices have the same intended use and same technological characteristics as the subject device. Moreover, the dimensions, material and technological characteristics of Stryker 1.5mm spiral routers are compared to the 1.5mm spiral router offered by Medtronic.

4100 E. Milham Ave.
Kalamazoo, MI 49001
t: 269 323 7700 f: 269 389 5412
www.stryker.com

Indications for Use:

The Footed Attachments and Cutting Accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE®) Console and electric and pneumatic motors. When used with these motors, the Footed Attachments and Cutting Accessories are intended to cut bone in the following manner: drilling, reaming, decorticating, shaping, dissecting, shaving and shaping for the following medical applications: Neuro; Spine; Ear, Nose, and Throat (ENT)/Otology/Neurotology/ Otorhinolaryngology; Craniofacial(bones of the skull and supraorbital region); and Sternotomy.

Specific applications include Craniotomy/Craniectomy, Pterional Craniotomy, Sub Occipital/Retro Sigmoid/Posterior Fossa Craniotomy, Sphenoid Wing Dissection, Laminotomy / Laminectomy, and Orthopedic Spine.

These devices are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices.

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Device Description: Footed Attachments are prescription medical devices that are designed to provide an interface between a cutting accessory and a high speed motor. When used with a motor and a cutting accessory, the Footed Attachments are intended cut, drill, ream, dissect and shape bone in a variety of surgical procedures including the following specialty areas:

Neuro, Spine, ENT, Sternotomy and Orthopedics.

The Stryker Footed Attachments are available in footed and non-footed configurations. The primary difference is the addition of the foot feature at the end of the nose tube.

The footed attachment is offered in two configurations: Fixed Footed Attachments and Rotating Footed Attachments. The primary difference between the Fixed and the Rotating Footed Attachment is the ability to rotate the foot portion of the device independently from the motor.

Cutting accessories are single use, sterile devices which have a mount or notch machined at their proximal end and a head with a sharp cutting edge at their distal end. The cutting accessories when used with a high speed drill and Footed Attachments are intended to cut, drill, ream, decorticate, shape, dissect, shave and smooth bone in a variety of surgical procedures.

Performance Data (Non Clinical Tests): The following verification tests were performed which demonstrate that the device meets the performance requirements under its indications for use conditions.

- Life Testing – Fluted Bur cutting accessories
- Life Testing – Spiral Routers
- Life Testing – Tapered and Straight cutting accessories
- Life testing – Diamond bur cutting accessories
- Temperature Testing – Bur Cutting Accessory
- Temperature Testing – Router Cutting Accessory
- Life, Functional and Graphics Testing of Footed Attachments
- Attachment Latch Test

Results of these tests demonstrate that the functionality, integrity, and safety and effectiveness of the Stryker Footed Attachments and Cutting Accessories is sufficient for their intended use and support a determination of substantial equivalence.

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Biocompat-ibility Tests: Stryker Footed Attachments and Cutting Accessories are classified as external communicating devices: tissue/bone/dentin with limited patient contact (< 24 hours).

The biocompatibility evaluation was conducted in accordance with AAMI/ANSI/ISO ISO 10993-1:2009/(R)2013, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, and Guidance for Industry and FDA Staff, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," dated April 23, 2013.

Results of testing validate that the subject devices are non-cytotoxic, non-sensitizing, a negligible irritant, non-toxic, and non-pyrogenic.

Table 1: Overview of Biocompatibility Testing

Tests Performed	Biocompatibility Test	Conclusions
Biocompatibility Testing	Cytotoxicity	Non-cytotoxic
	Sensitization	Non-sensitizing
	Irritation	Negligible irritant
	Acute Systemic Toxicity	Non-toxic
	Material Mediated Pyrogenicity (Attachments)	Non-pyrogen
	Bacterial Endotoxin Testing (Cutting Accessories)	Requirement met
	Colorant Leachables	Pass

Clinical Tests: No clinical testing was deemed necessary for this 510(k).

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Kalamazoo, MI 49001
t: 269 323 7700 f: 269 389 5412
www.stryker.com

Table 2: Comparison of Subject, Predicate and Reference Devices

Feature	Subject Device - Stryker® – Footed Attachments and Cutting Accessories	Predicate Device – Stryker CORE® (Duraguards, Routers and Burs) (K112593)	Reference Device - Anspach Dissecting Tools (K113476)	Reference Device - Medtronic Footed Attachments and Cutting Tools (K081475)	Justification
Model Name	Footed Attachments	Fixed Duraguards	Not applicable as 510k is for Cutting Accessories only	Footed Attachments	Similar Verification and Validation testing has demonstrated that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices.
	Rotating Footed Attachments	Steering Duraguards	Not applicable as 510k is for Cutting Accessories only	Rotating Footed Attachments	
	Non-Footed Attachments; 8cm and 9cm	D-Attachment	Not applicable as 510k is for Cutting Accessories only	Non-Footed Attachments 8-B and 9-M	
	Tapered, Spiral, Straight routers	Tapered routers	Tapered, Spiral routers	Tapered, Spiral, Straight routers	
	Match Head and Diamond Match Head cutting accessories	None	Not applicable for these cutting accessory head types	Match Head and Diamond Match Head cutting accessories	
Patient Population	General	General	General	General	Identical
Contra-indications	None	None	None	None	Identical

Feature	Subject Device - Stryker® – Footed Attachments and Cutting Accessories	Predicate Device – Stryker CORE® (Duraguards, Routers and Burs) (K112593)	Reference Device - Anspach Dissecting Tools (K113476)	Reference Device - Medtronic Footed Attachments and Cutting Tools (K081475)	Justification
Indications for Use statement	The Footed Attachments and Cutting Accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE®) Console and electric and pneumatic motors. When used with these motors, the Footed Attachments and Cutting Accessories are intended to cut bone in the following manner: drilling, reaming, decorticating, shaping, dissecting, shaving and smoothing for the following medical applications: Neuro; Spine; Ear, Nose, and Throat (ENT) / Otology /Neurotology/Otorhinolaryngology; Craniofacial (bones of the skull and supraorbital region); and Sternotomy. Specific applications include Craniotomy/Craniectomy, Pterional Craniotomy, Sub Occipital/Retro Sigmoid/Posterior Fossa Craniotomy, Sphenoid Wing Dissection, Laminotomy/Laminectomy, and Orthopedic Spine. These devices are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices.	The Stryker® Consolidated Operating Room Equipment (CORE) System is intended for use in the cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to dental, ENT (ear, nose, throat), neuro, spine, and endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.	Dissection tools are intended for cutting and shaping bone including spine and cranium.	The Electric Drill System is indicated for the incision / cutting, removal, drilling, and sawing of soft and hard tissue and bone, and biomaterials in the following applications: • Neurosurgical (Cranial, Craniofacial), • Spinal • Arthroscopic • Orthopedic • Sternotomy • General Surgical Procedures	Similar. The intended use of all the devices identical; to cut bone. The specific indications that are being proposed for addition are a subset of already cleared indications for the predicate devices. Verification and Validation testing has demonstrated that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices.

4100 E. Milham Ave.
Kalamazoo, MI 49001
t: 269 323 7700 f: 269 389 5412
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Feature	Subject Device - Stryker® – Footed Attachments and Cutting Accessories	Predicate Device – Stryker CORE® (Duraguards, Routers and Burs) (K112593)	Reference Device - Anspach Dissecting Tools (K113476)	Reference Device - Medtronic Footed Attachments and Cutting Tools (K081475)	Justification
Attachment Material	17-4 Stainless Steel (SST)	17-4 Stainless Steel (SST) and 13-8 MO Stainless Steel (SST)	N/A – Attachments not referenced	17-4 Stainless Steel (SST)	Identical
Attachment Packaging	Packaged in a sealed Korrvu retention insert	Packaged in a sealed Korrvu retention insert	Not applicable as 510k is for Cutting Accessories only	Wrapped in a Low Density Polyethylene bag and placed in a One Piece Folder E-flute corrugated carton	Similar
Sterilization Method	Supplied non-sterile. Sterilized at the user facility by steam sterilization.	Supplied non-sterile. Sterilized at the user facility by steam sterilization.	N/A – Attachments not referenced	Supplied non-sterile. Sterilized at the user facility by steam sterilization.	Identical
Model Name	Footed Attachments	Fixed Duraguards	N/A – Attachments not referenced	Footed Attachments	Similar
	Rotating Footed Attachments	Steering Duraguards	N/A – Attachments not referenced	Rotating Footed Attachments	Similar
	Non-Footed Attachments (8cm and 9cm)	D-Attachment	N/A – Attachments not referenced	Non-Footed Attachments (8-B and 9-M)	Similar
	Tapered, Spiral, Straight Routers	Tapered, Straight Routers	Fluted Spiral, Fluted	Tapered, Spiral, Straight Routers	Identical
	Match Head and Diamond Match Head cutting accessories	Match Head and Diamond Match Head cutting accessories	None	Match Head and Diamond Match Head cutting accessories	Identical

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Feature	Subject Device - Stryker® – Footed Attachments and Cutting Accessories	Predicate Device – Stryker CORE® (Duraguards, Routers and Burs) (K112593)	Reference Device - Anspach Dissecting Tools (K113476)	Reference Device - Medtronic Footed Attachments and Cutting Tools (K081475)	Justification
Attachment configuration	• Fixed Footed • Non-Footed • Rotating Footed	• Fixed Footed • Non-Footed • Rotating Footed	Not applicable as 510k is for Cutting Accessories only	• Fixed Footed • Non-Footed • Rotating Footed	Identical
Knurling on the surface of the Attachment	Yes	No	Not applicable as 510k is for Cutting Accessories only	Yes	Similar to predicate. Identical to reference. Verification and Validation testing has demonstrated that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices.
Footed Attachment Size	12mm-25mm	12mm-25mm	12mm-25mm	12mm-25mm	Identical
Type of Router	Tapered, Straight, Spiral	Taper, Straight	Tapered, Spiral	Tapered, Straight, Spiral	Similar
Type of Bur	Match Head, Diamond Match Head	Match Head, Diamond Match Head	None	Match Head, Diamond Match Head	Identical

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Conclusion

The subject Stryker® Footed Attachments and Cutting Accessories have the same fundamental scientific technology, intended use, functional characteristics and applications and therefore have a similar safety and effectiveness profile as the legally marketed predicate devices.